

Application No. 10/021,407

REMARKS/ARGUMENTS

Claims 5-8 and 13-18 are rejected under 35 USC 112. Claims 5-8 and 13-18 remain pending.

Claim Objection: Claim 15 was objected to for using a British variation of "artifact". Claim 15 is amended to recite the word "artifact".

Claim 5 is amended to recite that the needle includes a cutter lumen, and that the side port for receiving a tissue sample communicates with the cutter lumen. Support is found in the drawings as filed. No new matter is added.

102 Rejection of Claims 5 and 6

Claims 5 and 6 are rejected as anticipated by US 4,431,426 to Groshong et al. This rejection is improper for at least the following reasons.

Anticipation requires that a single prior art reference teach each and every element and limitation set forth in a claim. It is respectfully urged that Groshong et al. does not teach a biopsy device, as set forth in Claims 5 and 6. Instead Groshong et al. discloses an apparatus for use in intravenous therapy (eg. for administering nutrients intravenously, see for example Column 3, lines 8-14 of Groshong et al.).

In particular, it is respectfully urged that Groshong et al. does not teach or suggest a needle having a cutter lumen, or a side port for receiving a tissue sample. Note that the element 12 of Groshong that the Examiner notes as being a "side port for receiving tissue" is in fact a one way valve 12 (See column 5, lines 39-45). The valve opens when the fluid pressure inside the catheter is greater than the fluid pressure outside the catheter, per the teaching of Groshong et al. Accordingly, it is respectfully urged that Groshong does not teach or suggest a side port for receiving a tissue sample, but instead

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teaches a one way valve for controlling flow in an intravenous application. Nor does Groshong disclose a needle having a cutter lumen. Additionally, it is respectfully urged that Groshong et al. does not teach or suggest that the valve 12 be used in or be suitable for receiving a tissue sample, or that the catheter of Groshong et al. should or could be sized to receive a tissue cutter. Accordingly, the rejection of Claims 5 and 6 should be withdrawn.

102 Rejection of Claim 15

Claim 15 is rejected as anticipated by Miller et al. This rejection is improper for at least the following reasons.

Claim 15 recites, among other things:

a non-metallic elongated needle having a distal end, a proximal end, a longitudinal axis therebetween, the needle comprising a cutter lumen, a vacuum lumen, and a side port spaced from said distal end of said elongated needle for receiving a tissue sample;

The Examiner states that Miller discloses a needle that includes a cutter lumen 27 and a vacuum lumen 17. It is respectfully urged that the Examiner has mischaracterized Miller et al.

Miller et al. discloses an outer cannula 15 and an inner cannula 17. At page 4, paragraph 58, Miller discloses that the cutting element 11 includes an inner cannula 17 that fits concentrically within the outer lumen 27 of the outer cannula 15. At paragraph 61, Miller goes on to explain that inner cannula 17 defines an inner lumen 34. Accordingly, Miller et al. does not teach a needle having both a cutter lumen and a vacuum lumen as recited in Claim 15.

See Figures of the present application which illustrate a needle having both a cutter lumen 32 and a vacuum lumen 34. (c.g. Figure 2).

The Examiner is respectfully requested to withdraw this rejection, or alternatively, point out in a non final action how Miller et al. teaches a needle that includes both a

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cutter lumen and a vacuum lumen, so that the Applicant has an full and fair opportunity to respond.

103 Rejection of Claims 5 and 8-14

Claims 5 and 8-14 are rejected as obvious over Miller et al. in view of US Patent 5,534,778 to Loos et al. This rejection is improper for at least the following reasons.

Claim 5 recites, among other things,

a sharpened closed distal tip for insertion within tissue, said sharpened distal tip attached to said distal end of said needle, said distal tip having a hollow cavity which is at least partially filled with a material which will leave an artifact under magnetic resonance imaging, wherein said material is spaced distally from said side port of said needle.

It is respectfully urged that neither Loos et al. nor Miller et al. teach or suggest a sharpened closed distal tip attached to the distal end of a needle, the distal tip having a hollow cavity at least partially filled with a material which will leave an artifact.

The Examiner admits that Miller et al. does not teach a distal tip having a cavity in which the artifact creating material is disposed.

The Examiner refers to Figure 8 of Loos, and states that it would have been obvious to one having ordinary skill in the art to modify the distal tip of Miller et al. to contain a hollow cavity. However, the hollow needle 85 of Loos et al. does not appear to have a closed distal tip (see Figure 8), nor a side port.

First, it is respectfully urged that the Examiner has not provided the required motivation for making such a combination, other than to say "it would have been obvious to one of ordinary skill in the art to modify the tip of Miller et al...." It is respectfully urged that this is no more than improper hindsight reconstruction of the Applicant's invention by picking an choosing various elements from different documents. It is respectfully

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urged that the Examiner is required to explain where in the prior art there is motivation to make such a combination.

Further, even if one combined the references as suggested by the Examiner, it is respectfully urged that the resulting combination would not provide the claimed invention. This is because, among other things, the needle 85 of Loos et al does not provide a distal closed tip. Accordingly, modifying the tip of Miller et al. by the teachings of Loos et al. as suggested by the Examiner would not result in the invention of Claim 5 because the resulting combination would not have, among other things, a distal closed tip. Accordingly, withdrawal of the rejection of Claim 5 is requested.

Likewise, with respect to Claim 14, Claim 14 recites among other things:

a sharpened closed distal tip for insertion within tissue, said sharpened distal tip attached to said distal end of said needle, said distal tip having a cavity therein;

It is respectfully urged that one would not be motivated to combine Miller et al. and Loos et al. as suggested by the Examiner. However, even if one made such a combination, it is respectfully urged that the resulting combination would not teach or suggest a sharpened closed distal tip, the distal tip having a cavity therein.

Claim 6 is rejected as obvious over Miller et al. and Loos et al. as applied to Claim 5, and further in view of Gillies et al. It is respectfully urged that this rejection is improper for the reasons set forth above with respect to Claim 5.

Claim 7 is rejected as obvious over Miller et al. and Loose et al. as applied to Claim 5, and further in view of Werne. It is respectfully urged that this rejection is improper for the reasons set forth above with respect to Claim 5.

Claim 16, which depends from Claim 15, is rejected as obvious over Miller et al. in view of US 6,272,370 to Gillies et al. This rejection is improper for at least the reasons set forth above with respect to the rejection of Claim 15 as anticipated by Miller

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et al. In particular, even if one combined the references as suggested by the Examiner, the resulting combination would not provide both a cutter lumen and a vacuum lumen.

Similarly, the rejection of Claims 17 and 18 (which depend from Claim 15) as obvious over Miller et al. in view of Werne is improper for the reasons set forth above with respect to the rejection of Claim 15 as anticipated by Miller et al.

Reconsideration and allowance of the Claims is requested. The Examiner is requested to call the undersigned if the Examiner has any question or would like to discuss the claims, as amended.

Respectfully submitted,

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